Wyeth

Wyeth Pharmaceuticals

2235 '03 APR 29 A9:32

Date: April 28, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1060
Rockville, MD 20852

Re: Docket Nos. 03D-0060, 99D-1458, 00D-1538, 00D-1543, 00D-1542, & 00D-1539: Draft Guidance for Industry on "Part 11, Electronic Records, Electronic Signatures -- Scope and Application;" Availability of Draft Guidance and Withdrawal of Draft Part 11 Guidance Documents and a Compliance Policy Guide

Dear Sir/Madam:

Wyeth Pharmaceuticals is submitting the enclosed comments on the draft guidance for industry entitled, "Part 11, Electronic Records, Electronic Signatures -- Scope and Application" (68 FR 8775; February 25, 2003).

Wyeth is one of the world's largest research-based pharmaceutical and healthcare products companies, and is a leading developer, manufacturer and marketer of prescription drugs and over the counter medications.

We are submitting the enclosed comments in duplicate. Wyeth appreciates the opportunity to comment on the above-mentioned draft guidance for industry, and trusts that the Agency will find these comments useful.

Sincerely,

Roy J. Baranello

Roy J. Baranello, Jr.
Assistant Vice President
Worldwide Regulatory Affairs

1 00D-1543 C 31

1